UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,494	07/10/2003	Ratan K. Chaudhuri	EMI-54	9716

23599 7590 01/10/2006

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
ARNOLD, ERNST V	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,494	CHAUDHURI ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) 5 and 7 is/are withdrawn from consideration.

5)☒ Claim(s) 35 is/are allowed.

6)☒ Claim(s) 1-4,6 and 8-34 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the REMARKS filed on 10/31/2005. Applicant has cancelled claim 7. Applicants arguments have been carefully considered by the Examiner. Applicant has amended claim 1 to include the limitations of claim 5 to overcome the 35 USC 102(b) art rejection over Ghosal US 6,124,268. The art rejection is withdrawn because Ghosal does not teach less than 0.01% by weight of Rutin in the composition.

However, the Applicants arguments over the 35 USC 103(a) art rejections have been considered but have not been found to be persuasive. Therefore, the claims remain rejected for the reasons of record and those set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal U.S. Patent No. 6,362,167 and Vatter et al. U.S. Patent No. 6,475,500.

Ghosal discloses an extract blend that comprises by weight 35-55% of Emblicanin-A and Emblicanin B; about 4-15% of Punigluconin; and about 10-30% of Pedunculagin; about 0-15% of Rutin and about 10-30% of tannoids of gallic/ellagic acid

(Column 8, lines 12-20). The Examiner considers 0.001 to 0.01% Rutin within the range 0 to 15% Rutin specified by Ghosal.

Ghosal does not expressly teach a composition comprising the antioxidant extract blend and a substantially anhydrous or non-aqueous liquid vehicle further comprising a sunscreening agent or bismuth oxychloride.

The features recited in applicant's claim 3 are noted. The difference between claim 3 and Ghosal is that Ghosal does not expressly disclose 20-35 wt% Emblicanin A and 10-20 wt% Emblicanin B. Ghosal discloses a combined amont of 35-55 wt% of the two ingredients, wich is sufficient to encompass the combined amounts of said ingredients in applicant's claim 3. Additionally, at for example, 40 wt% total of the two ingredients, as disclosed and suggested by Ghosal, equal amounts of the two ingredients would be 20 wt% each. Hence, given the variability of extract content, which would be expected by the ordinary skilled artisan in this field, the percentages of Emblicanin A and B as set forth in claim 3 would have been fairly suggested from Ghosal's teachings.

The maximum absorbance feature recited in applicant's claim 7 is noted. Nowhere else in applicant's disclosure is this feature explained any further. However, applicant does state that "present invention is applicable to all types of extracts of Phyllanthus emblica" (specification page 1, lines 14-15). Applicant also states that the cited reference by Ghosal does in fact disclose extracts of Phyllanthus emblica (specification page 1, lines 11-14). Therefore, given that Ghosal's extract contains the same exact antioxidants as required by applicant's claim 1, the analytical characteristics

set forth in applicant's claim 7 (dependent on claim 1) are presumed to be characteristics that must necessarily be present in Ghosal's extract and its antioxidants, particularly in view of applicant's statement that Ghosal's extract is suitable and further in view of absence of any other evidence regarding the maximum absorbance disclosure. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Vatter et al. disclose an anhydrous cosmetic composition that improves skin color, texture and feel which is prepared by mixing: DC9040 cross linked elastomer gel (a dimethicone gelling agent); cyclomethicone (a silicone oil); silica, titanium dioxide (a sunscreen agent), iron oxide (Ronasphere LDP); isoeicosane (permethyl 102A); alkyl methicone (DC AMS C30 wax) (a structural agent); iron oxides-silicone coated; and titanium dioxide-silicone coated (Column 30, lines 47-64 and Column 32, lines 5-6). Vatter et al. disclose that bismuth oxychloride is a suitable agent to add to the composition (Column 13, lines 9-10). Vatter et al. disclose that polyethylene glycol is a suitable humectant to add to the composition (Column 11, lines 60-61).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to produce an anhydrous composition comprised of the antioxidant composition of Ghosal, derived from the fruit of the *Emblica officinalis* plant containing

0-15% Rutin and the anhydrous skin lotion of Vatter et al. to produce the instant invention. One having ordinary skill in the art would have been motivated to do this because Vatter et al. suggest that antioxidants can be incorporated into the compositions of their disclosure (Column 23, lines 55-67).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Claim Rejections - 35 USC § 103

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,649,150 in view of Vatter et al. U.S. Patent No. 6,475,500.

U.S. Patent No. 6,649,150 (hereafter referred to as the 150' patent) discloses a powder composition consisting essentially of by weight: 20-35% Emblicanin A, 10-20% Emblicanin B, 15-30% Pedunculagin and 3-12% Punigluconin 0.001 to 0.01% by weight of Rutin, less than about 1% flavonoids, said weight percentages having an average deviation of not more than 10% (Claim 1; column 13, lines 37-42) and characterized by an optical density of 0.8 at wavelength 410 nm, 0.1 at wavelength 470 nm, 0.08 at wavelength 530 nm, 0.09 at wavelength 590 nm and 0.02 at wavelength 650 nm (Claims 11-15; column 14, lines 4-20). The 150' patent further discloses a formulation

according to claim 1 and a cosmetically or pharmaceutically acceptable carrier (Claims 5 and 17, column 13, lines 48-50 and column 14, lines 23-25). The powder of the composition consists of essentially over 40% by weight of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than about 1% by weight of flavonoids (Claim 18; column 14, lines 26-29) and the powder according to claim 18 can consist essentially of by weight 50-80% of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than about 0.06% by weight of flavonoids (Claim 19; column 14, lines 30-33). In addition, the formulation can further comprise a photoprotective agent (sunscreen) (Claim 8; column 13, lines 57-59).

The 150' patent does not expressly disclose an anhydrous composition comprising an antioxidant comprising over 40% by weight of hydrolysable tannins comprising Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and a substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant or expressly disclose the addition of bismuth oxychloride.

Vatter et al. is relied upon as described above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made modify the antioxidant composition of the 150' patent by mixing it in a non-aqueous substantially anhydrous liquid vehicle taught by Vatter et al. to produce the instantly claimed invention. One of ordinary skill in the art would have been motivated to do so because the 150' patent suggests that the composition can be formulated with a cosmetically or pharmaceutically acceptable carrier (Claim 5). One of

ordinary skill in the art would have found the disclosure of Vatter et al. and produced the instant invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Double Patenting

Claims 1-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 11-15 and 17-19 of U.S. Patent No. 6,649,150 in view of Vatter et al. U.S. Patent No. 6,475,500.

The 150' patent discloses a powder composition consisting essentially of by weight: 20-35% Emblicanin A, 10-20% Emblicanin B, 15-30% Pedunculagin and 3-12% Punigluconin 0.001 to 0.01% by weight of Rutin, less than about 1% flavonoids, said weight percentages having an average deviation of not more than 10% (Claim 1) and characterized by an optical density of 0.8 at wavelength 410 nm, 0.1 at wavelength 470 nm, 0.08 at wavelength 530 nm, 0.09 at wavelength 590 nm and 0.02 at wavelength 650 nm (Claims 11-15). The 150' patent further discloses a formulation according to claim 1 and a cosmetically or pharmaceutically acceptable carrier (Claims 5 and 17). The powder of the composition consists of essentially over 40% by weight of Emblicanin

A, Emblicanin B, Pedunculagin and Punigluconin and less than about 1% by weight of flavonoids (Claim 18) and the powder according to claim 18 can consist essentially of by weight 50-80% of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than about 0.06% by weight of flavonoids (Claim 19). In addition, the formulation can further comprise a photoprotective agent (sunscreen) (Claim 8).

The 150' patent does not expressly disclose an anhydrous composition comprising an antioxidant comprising over 40% by weight of hydrolysable tannins comprising Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and a substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant or expressly disclose the addition of bismuth oxychloride.

Vatter et al. is relied upon as described above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made modify the antioxidant composition of the 150' patent by mixing it in a non-aqueous substantially anhydrous liquid vehicle taught by Vatter et al. to produce the instantly claimed invention. One of ordinary skill in the art would have been motivated to do so because the 150' patent suggests that the composition can be formulated with a cosmetically or pharmaceutically acceptable carrier (Claim 5). One of ordinary skill in the art would have found the disclosure of Vatter et al. and produced the instant invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie

obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Response to Applicants Arguments

1. Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal U.S. Patent No. 6,362,167 and Vatter et al. U.S. Patent No. 6,475,500. Applicant argued that one of ordinary skill in the art would have considered 0-15% to be an anomaly and not a true description of the amount of Rutin in the extract. The Examiner interprets the claims as they read given the broadest most reasonable interpretation of the claim. Claim 3 of US 6,362,167 recites 0-15% of Rutin and the Examiner must interpret the claim language as such. The Examiner cannot invalidate US 6,362,167. Therefore, claim 3 of US 6,362,167 anticipates the instantly claimed range of 0.001 to 0.01% Rutin by weight.

2. Applicant argued that one of ordinary skill in the art would not be motivated to change the aqueous formulation of the water soluble extracts and then incorporate the particular bismuth oxychloride for the purposes of improving skin feel. The Examiner respectfully maintains that one of ordinary skill in the art at the time the claimed invention was made would have been motivated to use the antioxidant plant extracts of Ghosal in the anhydrous cosmetic composition of Vatter. The choice of bismuth oxychloride having a particle size of less than 35 microns (80% within range) and a median size of 8 to 20 microns is deemed merely a matter of judicious selection of

commercially available products, acknowledged by the applicant as Biron (LF®-2000), which is well within the purview of one of ordinary skill in the art. Bismuth oxychloride is established in the art as an inexpensive product, which exhibits a controlled pearlescent effect (See: Kaufman US 3,822,141; column 1, lines 65-67). Bismuth oxychloride is established in the art as an ingredient in anhydrous compositions (See: Brieva et al. US 6,103,250; column 5, lines 1-6 and column 11, Examples 4 and 5; and Arraudeau et al. US 4,820,510; claims 9 and 13). The improvement of skin feel is an inherent property of bismuth oxychloride and anyone using a product containing bismuth oxychloride would have had that benefit. The 6,362,167 patent discloses that suitable formulations for skin care include lotions, creams or gels thus establishing different physical compositions, that may or may not be aqueous, that contain the antioxidant materials (Column 7, lines 28-34).

3. Applicant argued that Dr. Chadhuri is a co-inventor of US 6,649,150 and the there is a joint Assignee of the patent and present application. Applicant argued that Dr. Chadhuri improved the present invention so that the formulation is now anhydrous rather than aqueous. The inventive entity is different between the instant application and US 6,649,150 patent thus making Applicants arguments moot. The Examiner respectfully maintains, as discussed above, that anhydrous formulations are known in the art and one of ordinary skill in the art would know and have motivation to include the antioxidants of the instant invention in an anhydrous composition.

Conclusion

Claim 35 has been found to be free of the prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA

JOHN PAK
PRIMARY EXAMINER
GROUP 1600